

EFFECTIVENESS OF THERAPEUTIC HYPERTHERMIA BY CAPACITIVE-RESISTIVE ELECTRIC TRANSFER FOR DEGENERATIVE NECK PAIN

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ABSTRACT:

The main objective was to evaluate the effectiveness of INDIBA, S.A.'s, non-invasive hypothermia system by radio frequency based on Capacitive-Resistive Electric Transfer for the treatment of degenerative neck pain in comparison with the common treatment for this disease using phonophoresis.

A secondary objective was to evaluate the patients' tolerance and acceptance to the treatment.

Materials and Methods:

A prospective, single-centre, phase IV, open, controlled, randomized, parallel-group study. The research plan was designed in accordance with the AGEMED norm, which regulates the clinical research of health products, and approved by the Hospital Ethics Committee.

A total of 100 participants were recruited (50 for each treatment group) from visits at the Department of Physical Medicine and Rehabilitation at the University of Valencia Hospital Clinic. The patients assigned to treatment group A (with the hyperthermia equipment MD-308) received the treatment according to the following scheme. Application of the capacitive electrode for five minutes followed by the application of the resistive electrode for ten minutes per session. The treatment consisted of one session a day for five consecutive days, followed by a two-day pause and then another daily session for five consecutive days. Total of 10 sessions. When necessary (because the condition was not cured or it was only partially cured), an additional session was administered every other day for six days. The maximum period allowed for treatment of the disease being studied was one month.

Patients in group B were treated with the treatment usually given in the Department of Physical Medicine and Rehabilitation, which consists of six-minute sessions of phonophoresis using an ultrasound dose 0.2 W/cm². The treatment comprised one session a day for five consecutive days, followed by a two-day pause and then another daily session for five consecutive days. Total of 10 sessions.

Efficacy parameters:

Pain evaluation: By means of the Visual Analogue Scale (VAS) from 0cm to 10cm, where "0" means no pain and "10" means very severe pain. The VAS was completed by the patients before and after the treatment sessions. Pain was measured using the following variables:

Daytime pain, long term pain, provoked pain, spontaneous pain.

Additional evaluations:

Dizziness, occasional paresthesia, movement limitations in flexion/extension, rotations and lateral flexions according to the Maigne technique, other pre- and post-treatment signs and symptoms, record of any concomitant medication.

Results:

The percentage of patients without pain increases as the sessions continue in both the patients treated with CRET and those treated with ultrasound, with a clearer improvement between the first and last visits in those patients treated with CRET. The percentage of patients that improve with respect to daytime pain and long term pain is greater for those treated with CRET.

Both treatments improve provoked pain throughout all of the sessions; however, CRET acts faster, improving pain in more visits and from the beginning in a statistically significant manner ($p < 0.005$) whereas with ultrasound, statistical significance is not reached until visits 6 and 10 (end). There once again appears to be a trend favoring CRET, yet without reaching statistical significance.

With respect to spontaneous pain, CRET acts faster, with improvement beginning from the first session, and the improvement is more sustainable than with ultrasound (statistically significant intra-group difference).

INDIBA's method of hyperthermia by Capacitive-Resistive Electric Transfer (CRET) has proved to be an effective and safe method for treating degenerative neck pain in comparison with ultrasound (the common treatment for this problem), showing faster analgesic efficacy.